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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/697,473	CHOPRA, SHAM	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are presented for examination

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Status of the Claims

Applicants' amendment filed 10/31/2007 has been received and entered into the application. Accordingly, claims 1, 2, and 25-28 have been amended.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

As noted in the Office Action mailed 1/8/2007, no support for the instant claims is found in Applicants' prior-filed application nos. 60/293,701 (filed 5/25/2001), 10/085,234 (filed 2/28/2002), or 10/430,142 (filed 5/6/2003). Specifically, the prior-filed applications fail to

provide adequate support for the instantly claimed chronotherapy tablet having a cylindrical core, including the specific formulations and embodiments recited in the dependent claims. Further, the doses recited in claims 15-16, 19-20 and 23 are not supported in any of the prior-filed applications.

As such, the earliest effective U.S. filing date of the instant claims has been determined to be 10/30/2003, the filing date of the instant application.

Response to Arguments

Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection. However, in the interest of a complete prosecution history and in view of the fact that the newly cited prior is closely related to the previously cited prior art, the Examiner will address Applicants' arguments herein.

Firstly, Applicant argues that the language of the claims now pending do not encompass embodiments which exhibit a protruding section of the core as disclosed in Conte *et al.* (USP No. 4,865,849). However, newly cited USP No. 6,294,200 (also to Conte *et al.*) teaches pharmaceutical tablets having a core with an external partial coating in which said core consists of three layers (Abstract; Figure 2).

Secondly, Applicant argues that the chronotherapy tablets of the invention are manufactures by compression of granulations and compression coating and thus there can be no protruding section in multilayer tablets made on a multilayer compression machine and coated on a compression coating machine. However, newly cited USP No. 6,294,200 teaches tablets having a core consisting of three layers and obtained by compression (col. 2, lines 18-19) and

having a polymeric coating of the lower and lateral surface obtained by compression (col. 2, lines 36-39; Figure 2).

Thirdly, Applicant refers to the 37 C.F.R. § 1.132 Declaration of Dr. Desjardins, which purports to demonstrate that the tablets of previously cited Conte (USP No. 4,865,849) have a different release profile as the claimed tablets. However, newly cited USP No. 6,294,200 (also to Conte) demonstrates a tablet that has substantially identical release profile as that shown for the claimed tablets in the Desjardins Declaration (Table VI).

Accordingly, the Examiner is herein applying newly cited prior art (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997) to the instant claims. It is the Examiner's position that this newly cited art better describes tablets that are substantially similar to the claimed chronotherapy tablets.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, and 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by **Conte *et al.*** (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997).

The instant claims recite a tablet comprising a cylindrical core comprised of at least two superposed layers of different compositions and a compression coating which envelops the core except for at least one exposed release face of the core at at least one end of the core.

Conte *et al.* teach pharmaceutical tablets comprising a core with an external partial coating in which said core consists of three layers, wherein the upper layer contains an amount of the active substance with suitable excipients, the intermediate layer consists of polymeric material with retarding barrier function, and the lower layer contains the remaining amount of the active substance with suitable excipients and said external coating consists of controlled permeability polymeric materials, applied by compression to the lower surface and the lateral surface of the core (Abstract). The reference thus reasonably teaches a tablet comprising a "cylindrical core" having at least two layers of different compositions and a compression coating which envelops the core except for one exposed release face of the core as recited in claim 1(see especially Figure 2).

With respect to instant claim 2, which recites the limitation wherein the coating comprises water-soluble pore-forming material that remains intact throughout the release period but disintegrates prior to evacuation, Conte *et al.* teach that the coating of their invention consists of polymeric material able to form a payer impermeable to aqueous medium for a period of time predeterminable by suitable in vitro tests (col. 3, lines 47-51). Further, the coating shows a strength to the erosion and/or to the gelification and/or to the dissolution able to assure an adequate protection of the core from the contact with the external medium for a period of time necessary to the release of active substance both from the upper layer and from the lower layer of the tablets (col. 3, lines 52-57).

With respect to the limitations of instant claims 3-4, 6-8, and 10-11, Conte *et al.* teach that the intermediate layer is a "barrier layer" which determines a time interval between the release of the active substance contained in the upper layer and the lower layer, thus reasonably

teaching a "delay layer" as instantly claimed (col. 3, lines 25-39). Further, Conte *et al.* teach that the lower layer may have the same composition as the upper layer and contain the same of different active substance from that contained in the upper layer, thus teaching two layers of different compositions as well as two layers of the same composition as instantly claimed (col. 6, lines 4-9).

Conte *et al.* thus teach the limitations of claims 1-4, 6-8, and 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 9, and 12-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Conte *et al.*** (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997) as applied to claims 1-4, 6-8, and 10-11 above, and further in view of **Conte *et al.*** (USP No. 4,865,849; Issued Sep. 12, 1989).

Conte *et al.* ('200) teach as discussed *supra*. The reference does not teach tablets having two release faces of the core as recited in claim 5, tablets wherein the first layer is a barrier layer as recited in claim 9, or tablets having more than two active agent containing layers and more than one delay layer as recited in claims 12-17.

However, Conte *et al.* ('849) disclose a tablet for pharmaceutical use able to release active substances at successive times, comprising a first layer containing a portion of active substance, a barrier layer which is interposed between the first layer and a third layer containing the remaining portion of active substance (Abstract). Said barrier layer and third layer are housed in a casing, thereby allowing the part of active substance not inserted into the casing to be immediately available for dissolving (*id.*).

With respect to instant claims 9, 12 and 17 Conte *et al.* ('849) teach that the tablet can consist of more than two deposits of active substance separated from each other by layers of polymeric material (*i.e.* barrier or delay layers) (col. 2, lines 11-19; Claim 6). The reference further teaches that the active substance can be of the same or different types in the various deposits of active material (*id.* and Claims 7 and 8). Conte *et al.* explicitly teach tablets comprising ibuprofen (Example 1), propanolol HCl (Example 2), indomethacin (Example 3) and naproxen (Example 4) as the active ingredients therein.

With respect to claim 9, Conte *et al.* ('849) disclose that the tablet taught therein can consist of more than two deposits (*i.e.* layers) of active substance separated from each other by layers of polymer material (*i.e.* delay or barrier layers) (col. 2, lines 11-19; Claim 6). Further, the active substance can be in the form of a single layer separated from the external environment by a layer of gellable and/or soluble polymer material (*id.*). As such, it would have been *prima*

facie obvious to modify the tablet of Conte *et al.* ('200) to form a tablet comprising a first layer that is a delay layer (claim 9) and additional layers comprising active substance.

With respect to claim 13, both Conte references disclose tablets comprising the instantly claimed drugs (see Examples). Conte *et al.* ('849) further discloses tablets with multiple layers of active substances separated by one or more barrier layers. As such, it would have been *prima facie* obvious to formulate a multilayer tablet with a first layer that is a delay layer and subsequent layers containing active substances. This is especially true given that the Conte *et al.* ('849) explicitly contemplates a tablet wherein the active substances are separated from the external environment by a barrier layer (col. 2, lines 11-19).

With respect the instantly claimed limitation wherein the delay layers provide for substantially complete dissolution of the delay layer between about 5 to about 9 hours (*e.g.* claims 13 and 17), the references utilizes identical polymers to form the barrier layer as the instantly claimed tablets. For example, Applicant describes "dissolution rate modifiers" that include hydroxypropylmethylcellulose (page 17, lines 25-28). Conte *et al.* ('200) teaches that the barrier layer of their tablets comprise hydroxypropylmethylcellulose (col. 5, lines 29-31). Conte *et al.* ('849) further teach that the water penetrates the barrier layer at a rate controlled by the components of the barrier layer itself (col. 2, lines 30-33). The reference further discloses that the time for the barrier layer to be traversed by water is controlled not only by the composition but also by the thickness of the barrier (*id.* at lines 34-36). Thus, Conte *et al.* ('849) suggest that the dissolution rate of the barrier layer can be adjusted by changing its composition or thickness. For example, in the tablets exemplified in the reference, the barrier layer becomes progressively permeable to the disintegration liquid, to enable water, after a time of about 0.5 to

1 hours, to come into contact with the second layer of the system (col. 5, lines 42-46). It would have been *prima facie* obvious that adjusting the composition or thickness of the barrier layer would lead to an increased dissolution time of said barrier layer. Further, the Examiner notes that the limitation "between about 5 to about 9 hours" is very broad. As such, it could be interpreted to include the about 1 hour dissolution time disclosed in Conte *et al.* ('849). Further still, it is noted that Conte *et al.* ('200) demonstrate a tablet releasing 50% of active substance within 1 hour (*i.e.*, release of drug from the exposed active agent layer) after which about 8 hours passes with minimal drug release (*i.e.*, dissolution of barrier layer). Subsequently, the remaining drug is released from the second drug layer (Table VI).

With respect to claims 14-16, Conte *et al.* ('849) disclose a tablet comprising naproxen in a dose of 275 mg per layer (Example 4). Naproxen is "releasable" in about 15 minutes as instantly claimed (*e.g.*, 78% in 10 minutes and 88% in 15 minutes) (col. 12, lines 50-60). With respect to the third layer of naproxen being released as a constant rate over a period of about 5 hours, modifying the formulation of naproxen in said third layer would have been well within the level of ordinary skill in the art. It is noted that the prior art discloses various methods of modifying the release rate of drugs from pharmaceutical compositions. For example, Conte *et al.* ('849) specifically disclose that the rate of release of active substance from the layers containing it can be varied according to therapeutic needs by varying the composition of the layer concerned (col. 2, lines 61-64). For example, polymers, such as hydroxypropylmethylcellulose, can be added to the active drug layer to effect differing dissolution and release rate profiles (col. 3, lines 4-11). As such, Applicant's instantly claimed release profile amounts to routine optimization of the prior art compositions. The motivation to

modify the reference compositions to attain specific release rates of active substances is found in Conte *et al.* wherein they disclose that the rate of release of active substance can be modified to effect differing dissolution and release rate profiles.

As such, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the tablets of Conte *et al.* ('200) to have multiple active agent layers and multiple barrier layers as suggested and motivated in Conte *et al.* ('849). Further, as noted *supra*, modifying excipients and amounts of excipients to elicit a desired release profile is more than routine in the art of pharmaceutical preparation. In fact, both of the cited Conte *et al.* references demonstrate in the examples provided therein that changing excipients results in different release rates of active agents.

Claims 18-20, 24-25 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Conte *et al.*** (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997) and **Conte *et al.*** (USP No. 4,865,849; Issued Sep. 12, 1989) as applied to claims 5, 9, and 12-17 above, and further in view of **Geoghegan *et al.*** (U.S. Patent No. 5,219,621; Issued Jun. 15, 1993).

Conte *et al.* ('200) and Conte *et al.* ('849) disclose as discussed *supra*. While Conte *et al.* ('200) teach that diltiazem is a drug that may be incorporated into the disclosed tablets (col. 8, line 6), Geoghegan *et al.* is provided as further evidence that diltiazem is often formulated in a tablet dosage unit and further provides evidence that sustained release of diltiazem is advantageous..

Geoghegan *et al.* discloses that diltiazem is a benzothiazine derivative possessing calcium antagonist activity (col. 1, lines 18-21). It is further disclosed that diltiazem has been shown to

be useful in alleviating symptoms of chronic heart disease, particularly angina pectoris and myocardial ischemia and hypertension (*id.* at lines 21-27). Diltiazem is conventionally administered in tablet form (30 mg and 60 mg) as diltiazem HCl (*id.* at lines 27-29). Geoghegan *et al.* disclose a diltiazem pellet formulation for oral administration comprising a diltiazem core with a multi-layer membrane surrounding the core (Abstract). The number of layers in the membrane and the ratio of polymers are effective to permit release of diltiazem over an extended period of time (col. 2, lines 42-55). Diltiazem was administered to patients in a dose of 120 mg and reference diltiazem tablets at a dose of 60 mg (col. 12, lines 43-50).

With respect to the instantly claimed doses of diltiazem, the limitations "between about 25 mg – 100 mg" (claim 19), "between about 50 mg – 150 mg" (claim 20) and "between about 80 mg – 200 mg" (claim 21) are rendered obvious by the doses of 60 mg and 120 mg diltiazem that were administered to patients in Geoghegan *et al.*

With respect to the methods recited in instant claims 24-25 and 27, it is well known in the art that diltiazem is useful in the treatment of cardiovascular disease as evidenced in Geoghegan *et al.* As such, because the treatment of cardiovascular disease with diltiazem was well known in the art, it would therefore have been *prima facie* obvious at the time of the invention to use the instantly claimed dosage forms of diltiazem to treat cardiovascular disease.

Thus, it would have been *prima facie* obvious at the time the invention was made to formulate a multi-layer tablet as disclosed in the combined Conte *et al.* references with the drug diltiazem and use said tablet to treat a patient with cardiovascular disease. Geoghegan *et al.* provide evidence that diltiazem dosage units were known in the art and useful in the treatment of cardiovascular disease. As such, the skilled artisan would have been imbued with at least a

reasonable expectation that diltiazem could be used in the multi-layer tablet disclosed in the Conte *et al.* references. The substitution of one drug for another in a prior art drug formulation would have been *prima facie* obvious to the skilled artisan.

Claims 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Conte *et al.*** (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997) and **Conte *et al.*** (USP No. 4,865,849; Issued Sep. 12, 1989) as applied to claims 5, 9, and 12-17 above in view of **Dunn *et al.*** (U.S. Patent No. 4,525,345; Issued Jun. 25, 1985).

Conte *et al.* ('200) and Conte *et al.* ('849) disclose as discussed *supra*. The references do not explicitly disclose a method of treating arthritis.

However, Dunn *et al.* disclose a constant rate indomethacin formulation comprising 50 to 200 mg indomethacin (Abstract). Indomethacin, naproxen, and ibuprofen are recited as treatments of choice for arthritic patients (col. 1, lines 23-26). The reference further discloses a method of treating arthritis comprising administering an oral dosage form of indomethacin to a patient (claim 25).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate and administer an indomethacin multi-layer tablet suggested and motivated by the Conte *et al.* references to a patient suffering from arthritis. The skilled artisan would be motivated to do so because indomethacin is an art recognized treatment for arthritis as disclosed in Dunn *et al.* As such, the skilled artisan would have been imbued with at least a reasonable expectation that administration of a multi-layer indomethacin tablet to a patient suffering from arthritis would be an effective treatment. In fact, Conte *et al.* ('200) teach

that indomethacin is a drug that may be incorporated into the tablets disclosed therein (col. 7, line 61).

Claims 21-25 and 28 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over **Conte *et al.*** (USP No. 6,294,200; Issued Sep. 25, 2001; Filed Feb. 4, 1997) and **Conte *et al.*** (USP No. 4,865,849; Issued Sep. 12, 1989) as applied to claims 5, 9, and 12-17 above in view of **Le Roux *et al.*** (Respiration, 1991, vol. 58, pages 192-197).

Conte *et al.* ('200) and Conte *et al.* ('849) disclose as discussed *supra*. The references do not explicitly disclose a multilayer tablet formulation comprising the drug salbutamol or a method of treating asthma.

However, Le Roux *et al.* is provided as evidence that the instantly claimed doses and method of treating asthma with salbutamol were known in the art. Le Roux *et al.* disclose that a slow-release oral formulation of salbutamol (standard oral dose of 4 mg) was administered to asthma patients (Abstract). An 8 mg slow-release oral formulation of salbutamol was also administered to asthma patients (*id.*). It is noted that the 8 mg dose of oral salbutamol was more effective than the 4 mg dose.

With respect to the instantly claimed dose of salbutamol, the limitations "between about 2 mg to about 4 mg" (claim 23) are rendered obvious by the doses of 4 mg and 8 mg salbutamol that were administered to patients in Le Roux *et al.* Le Roux *et al.* also provide further motivation to administer a multi-layer tablet of salbutamol because they disclose that an oral dose of 8 mg was more effective than an oral dose of 4 mg. As such, the skilled artisan would

have been motivated to administer salbutamol in a dosage form that would lead to multi-phase release profile of the drug.

With respect to the methods recited in claims 24-25 and 28, it is well known in the art that salbutamol is useful in the treatment of asthma. As such, it would have been *prima facie* obvious at the time of the invention to use the instantly claimed dosage forms of salbutamol to treat asthma.

Thus, it would have been *prima facie* obvious at the time the invention was made to formulate a multi-layer tablet as suggested and motivated by the combined Conte *et al.* references with the drug salbutamol and use said tablet to treat patients with asthma. Le Roux *et al.* provide evidence that oral salbutamol dosage forms were known in the art and used to treat asthma patients. As such, the skilled artisan would have been imbued with at least a reasonable expectation that salbutamol could be used in the multi-layer tablets disclosed in the Conte *et al.* references. The substitution of one drug for another in a prior art drug formulation would have been *prima facie* obvious to the skilled artisan. In fact, it is noted that Conte *et al.* ('200) teach that salbutamol is a drug suitable for incorporation into the tablets taught therein (col. 8, line 12).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614